Supreme Court, U.S.
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No. ——

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ERNEST BERGER, Personal Representative
of the Estate of SHEILA BERGER,
Petitioner,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

Petition for a Writ of Certiorari to the Washington State Supreme Court

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Does the Supremacy Clause require a finding that Food and Drug Administration regulations pertaining to the labeling of tampons pre-empt state law compensatory schemes for injuries caused by inadequate warning and inadequate instruction?

Are State compensatory schemes "requirements with respect to a medical device" within the meaning of 21 U.S.C. § 360(k)(a) so as to be pre-empted by federal regulations drafted pursuant to the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 360(d) through 360(k)?

LIST OF PARTIES

Plaintiff is Ernest Berger as Personal Representative of the Estate of Shelia Berger.

Defendant is Personal Products, Incorporated, also known as or merged with Johnson & Johnson Baby Products and Johnson & Johnson Products, Incorporated, and Johnson & Johnson, Incorporated.

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PETITION FOR A WRIT OF CERTIORARI

OPINION BELOW

The opinion of the Supreme Court of the State of Washington, dated September 20, 1990, is reported at 115 Wn.2d 267 and is reproduced at pages 1a-10a of the Appendix to this Petition. The Mandate of the Supreme Court of the State of Washington is not reported and appears at Pet. App. 11a-12a. The order of the Washington State Supreme Court denying reconsideration, dated November 19, 1990, is not reported and appears at Pet. App. 13a. The Memorandum Opinion of the Super-

ior Court of the State of Washington, dated March 14, 1989, is not reported and appears at Pet. App. 14a-16a.

JURISDICTION

The judgment of the Supreme Court of the State of Washington was entered on September 20, 1990. Pet. App. 1a-10a. This Court has jurisdiction under 28 U.S.C. § 1257(3).

CONSTITUTIONAL PROVISIONS, STATUTES, AND RULES INVOLVED

This case involves the Supremacy Clause, Article VI, cl. 2, provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360(k); and federal regulations, 21 C.F.R. § 808.1.

The Supremacy Clause provides:

> This Constitution, and the laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The remaining statutory and regulatory materials are reprinted at Pet. App. 21a-26a.

STATEMENT OF THE CASE

This is a wongful death action by the personal representative of the Estate of Sheila Berger against Personal Products, Inc., the manufacturer of "o.b. tampons." Ms. Berger died on January 5, 1984, of toxic shock syndrome believed to be contracted as a result of using Defendant's tampon product. At the time of her death, Sheila was twenty years old.

Toxic shock syndrome is a rare but serious disease which can be fatal. 21 C.F.R. § 801.430. It is believed to be caused by a toxin-producing strain of bacteria called *Staphylococcus aureus*. Scientists also believe that the use of tampons enhances the growth of the bacteria. *Toxic Shock Syndrome, Recognition and Management of a Diverse Disease*, Postgraduate Medicine, Vol. 73, No. 1, January, 1983. Teenage girls and women under 30 years of age are reported to be more likely to develop tampon-associated toxic shock syndrome than menstruating women of other age groups. *Ibid.* Toxic shock syndrome has occurred in non-menstruating women. *Id.*

Significant evidence links the design of a manufacturer's tampon to the likelihood that the disease will be contracted. *The Relationship of Tampon Characteristics to Menstrual Toxic Shock Syndome*, The Infection Reporter, November, 1987, pp. 73-74. Generally, tampons which have greater absorbency provide increased opportunity for the bacterial growth which creates the toxin. *Ibid.*

Plaintiff brought this action alleging, *inter alia*, that Defendant's tampons were unreasonably dangerous because of inadequate warnings about the risk of contracting toxic shock syndrome. The manufacturer defended based on its compliance with federal regulations and the pre-emption doctrine.

The Medical Device Amendments to the Food and Drug Act, 21 U.S.C. §§ 360(d)-(k) grant the Food and Drug Administration broad authority over medical devices. Section 360(j)(h) of the Act specifically provides for the adoption of regulations for dissemination to the public concerning the safety and effectiveness of a device. Pursuant to this statutory authority, the FDA drafted regulations concerning the labeling of tampon products. It is not disputed that the Defendant complied with the federal regulations governing its product.

Defendant moved for summary judgment on the claim of inadequate warnings. It argued that 21 U.S.C. § 360

(k) pre-empted any state tort action based upon the adequacy of warning in those cases where the product complied with the federal regulations. The Yakima County Superior Court granted this motion for summary judgment. The Court's Memorandum Opinion appears at Pet. App. 14a.

Plaintiff then sought direct review in the Washington State Supreme Court. The Court granted review, but affirmed the decision of the trial court. The opinion of the Washington Supreme Court is reported at 115 Wn.2d 267 and appears at Pet. App. 1a-10a. Plaintiff filed a timely motion for reconsideration. This motion was denied in an unreported ruling. That ruling appears at Pet. App. 13a. The Washington State Supreme Court subsequently mandated the matter to the Yakima County Superior Court. The Court's unreported Mandate appears as Pet. App. 11a.

REASONS FOR GRANTING THE WRIT

I. THIS COURT SHOULD GRANT THE PETITION FOR WRIT OF CERTIORARI TO RESOLVE A SIGNIFICANT ISSUE PERTAINING TO THE SUPREMACY CLAUSE AND A STATE'S RIGHT TO PROVIDE COMPENSATION FOR VICTIMS OF INADEQUATELY LABELED PRODUCTS.

A. The Supremacy Clause, U.S. Const. Art. VI, cl. 2 Invalidates Only Those State Laws Which Interfere With or Are Contrary to Federal Law.

The Supremacy clause, U.S. Const. Art. VI, cl. 2 provides:

> This Constitution, and the laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Con-

stitution or Laws of any State to the Contrary notwithstanding.

In interpreting this section, this Court has long looked to whether state laws "interfere with or are contrary to federal law." *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23(1824). Under the Supremacy Clause, federal law may supersede state law in a variety of ways.

First, in enacting the federal law, Congress may explicitly define the extent to which it intends to pre-empt state law. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95-96 (1983). Express pre-emption may be found whenever Congress expressly states its intent to pre-empt or supersede state law. *Hillsborough County, Fla. v. Automated Medical Laboratories*, 471 U.S. 707, 713 (1985). Federal regulations have the same pre-emptive effect as federal statutes. *Fidelity Federal Savings & Loan Assn. v. De La Cuesta*, 458 U.S. 141, 153 (1982).

Second, in the absence of express pre-emptive language, the Court may imply or infer an intent to pre-empt where the statutory or regulatory scheme is sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Pre-emption of a whole field may also be inferred where the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. *Ibid.*; *Hines v. Davidowitz*, 312 U.S. 52 (1941).

Finally, state law is nullified to the extent that it creates an actual conflict with federal law. *Michigan Canners & Freezers v. Agricultural Bd.*, 467 U.S. 461, 469 (1984). "Such a conflict arises when compliance with both state and federal law is impossible. . . ." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). A conflict may also be found when the state law "stands as an obstacle to the accomplishment

and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. at 67 (1941).

B. The Medical Device Amendments to the Food, Drug and Cosmetic Act Do Not Expressly Pre-empt State Product Liability Law.

In 1976 Congress extended the Food, Drug and Cosmetic Act to cover all medical devices intended for human use. 21 U.S.C. §§ 360(d)-(k). Section 360(k)(a) of the Act contains the only statement pertaining to the relationship of the federal legislation to state law. That section provides:

> (a) General rule
>
> Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360(k)(a). Pet. App. 21a. Section (b) of the statute provides a mechanism by which a State may seek an exemption from the terms of the statute. 21 U.S.C. § 360(k)(b). These exemptions are available from the Secretary if the requirement is more stringent than a requirement under the chapter. 21 U.S.C. § 360(b)(1).

Pursuant to the authority of this statute, the Food and Drug Administration promulgated the following regulation:

> 808.1 Scope
>
> (b) Section 521(a) of the act contains special provisions governing the regulation of devices by States

> and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation or court decision) which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or any other matter included in a requirement applicable to the device under the act.

21 C.F.R. § 808.1(b), Pet. App. 22a.

The legislative history of the 1938 bill clearly manifests the intent of Congress to preserve state tort law remedies. The first draft of the 1938 legislation included a provision for a private federal right of action for damages for violations of the Act:

> Sec. 24. A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of the Act.

Hearings Before a Subcommittee of the Committee of Commerce, U.S. Senate, 73d Cong., 2d Sess., p. 10 (1933). However, this private cause of action was deleted from subsequent drafts on the ground that such a provision would duplicate already existing rights under state law. *See Consumer Federation of America v. Upjohn Co.*, 346 A.2d 725, 731 (D.C. App. 1975); *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364, 365 (S.D. Fla. 1971). As the legislative debate reveals, the adamant view was that "The party injured now has every reasonable protection under the law and a right of action for damages . . ." *Hearings Before a Subcommittee of the Committee of Commerce, U.S. Senate*, 73d Cong., 2d Sess., pp. 400, 403, 431 (1933).

The legislative history demonstrates not a debate over whether state tort law would survive under the FDCA

but rather a widely-held assumption that it would and that a federal cause of action would be duplicative. This history explains the Congressional silence in subsequent FDCA amendments concerning the effect of the legislation on state remedies. State tort remedies are so fundamental in our system of federalism that their survival was patently obvious.

In 1976, Congress attempted to address various deficiencies in the FDCA by enacting the Medical Device Amendments which would bring medical devices under the direct suporvision of the FDA.

In introducing the legislation, Senator Edward Kennedy succinctly states its purpose:

> The purpose of this legislation is to protect the health and safety of the American people . . . the legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions.

121 Cong. Rec. 59, 10688 (1975). The Congessional Reports accompanying the Medical Device Amendments contain little discussion of Sec. 360(k). The sole purpose of the pre-emption provision appears to be pre-emption of state drug and device laws which conflicted with the new federal regulatory scheme.

The absence of explicit legislative intent as to the Medical Device Amendments is not fatal to the argument against express pre-emption. The Court looks primarily to the express terms of the statute in determining issues of pre-emption. *Comment, Federal Preemption and the FDA: What Does Congess Want?*, 58 Cinn. L. Rev. 263, 265-266(1989).

Section 360(k) is virtually identical to a provision contained in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

> [A] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. 136(v)(b). The D.C. Circuit Court of Appeals interpreted the FIFRA pre-emption language as not pre-empting state tort actions or remedies based on the following reasoning:

> The verdict itself does not command Chevron to alter its label—the verdict merely tells Chevron that, if it chooses to continue selling paraquat in Maryland, it may have to compensate for some of the resulting injuries. That may in some sense impose a burden on the sale of paraquat in Maryland, but *it is not equivalent to a direct regulatory command that Chevron change its label. Chevron can comply with both federal and state law by continuing to use the EPA-approved label and by simultaneously paying damages to successful tort plaintiffs such as Mr. Ferebee.* (Emphasis added).

Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1541 (D.C. Cir.), *cert. denied*, 105 S.Ct. 545 (1984). Similarly, this Court should reject the contention that § 360(k) expressly pre-empts state product liability law.

C. Conflicting Decisions Exist as to Whether Compensatory Tort Systems Are Pre-empted by the Medical Device Amendments to the Food, Drug and Cosmetic Act and Regulations Promulgated Pursuant to Its Authority.

Courts which have been called upon to determine the pre-emptive scope of § 360(k) have reached conflicting results depending on the area of regulation being analyzed. In *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981), the court concluded the Act did not pre-empt a Florida statute governing information to be given purchasers of hearing aids. The New Jersey Supreme Court

reached the same result in *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (1978). There the court opined:

> In specifying a detailed formula for use in determining exactly which state laws are pre-empted by § 521 [§360(k)(a)], Congress has deliberately circumscribed the extent to which its enactment has occupied the field of device regulation. . . . [I]n view of the establishment of this innovative exemption mechanism, it seems accurate to say that there is nothing "implicitly contained in its structure and purpose" from which an unambiguous congressional intent to pre-empt concurrent state regulations is reasonably inferable.

New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 813-14.

This approach is different from that taken by courts analyzing regulations governing tampons. For instance, a different panel of the Fifth Circuit concluded federal regulations governing tampon labeling pre-empted state product liability law. *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989). No other circuit has specifically addressed the issue.

The Tenth Circuit, however, did affirm a large verdict awarded to a plaintiff in another toxic shock syndrome case. The plaintiff's chief complaint was that the product's warnings were inadequate. The Tenth Circuit rejected Defendant's argument that compliance with the federal standards immunized it from liability. The court noted:

> Playtex argues that the presence of a warning that complied with FDA requirements precludes, as a matter of law, any finding that Playtex exhibited the reckless indifference necessary to support an award of punitive damages. We disagree. As we noted above, compliance with FDA standards is not dispositive of Kansas law if a reasonable manufac-

> turer would have done more. Under these circumstances, compliance with FDA regulations does not preclude punitive damages when there is evidence sufficient to support a finding of reckless indifference to consumer safety.

Olgivie v. International Playtex, Inc., 821 F.2d 1438 (10th Cir. 1987).

Washington appears to be the first state supreme court to reach the issue. In *Berger v. Personal Products*, 115 Wn.2d 267 (1990), the Supreme Court of the State of Washington, followed the *Moore* analysis. It found Congress intended to pre-empt petitioner's state claim for damages based on allegations of improper or inadequate warnings.

The *Berger* opinion and other cases which find pre-emption conflict with this Court's analysis of pre-emption issues. Specifically, Washington failed to recognize that the language of § 360(k) is not sufficient to find an express or implied Congressional intent to pre-empt product liability law. This Court employs a strong presumption against a finding of pre-emption in those areas historically within the province of state and localities. "Where . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. at 230) (citations omitted). Consequently, to prevail on the pre-emption argument in a field relating to the States' historic police powers, the party urging pre-emption must present a showing of pre-emption that is strong enough to overcome the presumption "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough County, Fla. v. Automated Medical Laboratories*, 471 U.S. at 714.

Respondents cannot overcome this strong presumption. The Supreme Court of the State of Washington and the Fifth Circuit therefore erred in concluding product liability laws pertaining to inadequate warnings are preempted by federal law.

First, Section 360(k)(b) of the Act allows the existence of more stringent state requirements. Section 360(k) provides an application process for approval of state standards which exceed the federal minimum. That section provides:

> (b) Exempt Requirements
>
> Upon application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> > (1) The requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
> >
> > (2) the requirement—
> >
> > > (A) is required by compelling local conditions and,
> > >
> > > (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360(k)(b) Subsection (1) of the statute thus specifically allows state regulation when two conditions have been met. The regulation must be approved by the Secretary and the regulation must be stricter than that provided by the Act. Admittedly, Washington's tort laws have not been specifically approved by the Secretary of the Food and Drug Administration.

However, the second requirement has been clearly met. There is little doubt that Respondent's chief complaint concerning Washington's product liability law is that the jury is likely to impose a higher standard of care on the manufacturer of tampons than that contained in the FDA regulations. At minimum, this section of the statute rebuts the assumption that Congress intended to protect manufacturers against stringent state laws which impose higher burdens upon them. Moreover, § 360(b)(1) negates the argument that a more stringent state standard automatically conflicts with federal regulations.

Second, a finding of pre-emption conflicts with Food and Drug Administration interpretations of the Act. "The FDA's statement is dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent or subsequent developments reveal a change in that position." *Hillsborough County, Fla. v. Automated Medical Laboratories*, 471 U.S. at 714, citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984). In the present case, the FDA has taken the position that Congress did not intend to pre-empt state or local product liability law. In a letter to a Washington attorney, Joseph M. Sheehan, Chief of the FDA regulations staff, opined:

> [I]t is the Food and Drug Administration's (FDA) position that Section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) pre-empts only state and local requirements that are specifically related to medical devices. Therefore, the FDA believes that Section 521 does not pre-empt general product liability requirements.

Pet. App. 19a, *See also*, Pet. App. 17a-18a; 20a.

Finally, the opinion conflicts with this Court's holding in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). In *Silkwood*, this Court reversed an appellate court which had concluded that a state may not impose puni-

tive damages for the escape of radioactive material from a federally licensed nuclear facility. The evidence at trial established that Kerr-McGee had complied with most federal regulations promulgated by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act, 42 U.S.C. § 2011 *et seq.* Despite this compliance, the Court held that state punitive damage awards for nuclear accidents were not pre-empted by federal law.

This Court initially restated prior law which had held that the "Federal Government ha[d] occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the States." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. at 622. [Citing, *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983)] The Court then rejected arguments that the fact the federal government had completely occupied a field controlled the issue of pre-emption. It noted:

> We do not suggest that there could never be an instance in which the federal law would pre-empt the recovery of damages based on state law. But insofar as damages for radiation injuries are concerned, preemption should not be judged on the basis that the Federal Government has so completely occupied the field of safety that state remedies are foreclosed but only whether there is an irreconcilable conflict between the federal and state standards or whether the imposition of a state standard in a damages action would frustrate the objectives of federal law. We perceive no such conflict or frustration in the circumstances of this case.

Silkwood v. Kerr-McGee Corp., 464 U.S. at 625-26. Paying both federal fines and state imposed damages for the same incident, observed the Court, would not appear to be physically impossible. *Ibid.*

Justices Blackmun and Marshall dissented from this conclusion. Their dissent, however, merely took issue

with the Court's holding regarding punitive damages. As to compensatory damages, both Justices had no difficulty in concluding that federal law would not pre-empt such an award. The analysis employed in this dissent illustrates why courts err in concluding summarily that compensatory damages are pre-empted in a regulated field.

> It is true that the prospect of compensating victims of nuclear accidents will affect a licensee's safety calculus. Compensatory damages therefore have an indirect impact on daily operations of a nuclear facility. But so did the state statute upheld in *Pacific Gas*. The crucial distinction between compensatory and punitive damages is that the purpose of punitive damages is to regulate safety, whereas the purpose of compensatory damages is to compensate victims. Because the Federal Government does not regulate the compensation of victims, and because it is inconceivable that Congress intended to leave victims with no remedy at all, the pre-emption analysis established by *Pacific Gas* comfortably accommodates—indeed it compels—the conclusion that compensatory damages are not pre-empted whereas punitive damages are.
>
> . . . . Congress intended to rely solely on federal expertise in setting safety standards, and to rely on states and juries to remedy whatever injury takes place under the exclusive federal regulatory scheme. Compensatory damages therefore complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme.

Silkwood v. Kerr-McGee Corp., 464 U.S. at 629-30 (Justice Blackmun, dissenting).

The *Berger* opinion cannot be reconciled with these decisions of this Court. As noted below, this case provides an appropriate forum for correcting misinterpretation of the pre-emption doctrine as it applies to the Medical Device Amendments of the Food, Drug and Cosmetic Act.

D. The Present Case Is an Appropriate Vehicle for Clarifying the Pre-emption Doctrine as It Relates to the Food, Drug and Cosmetic Act, Medical Device Amendments, 21 U.S.C. §§ 360(d)-(k).

The Supreme Court of the State of Washington, like federal district courts before it, reasoned from the existence of comprehensive regulations regarding tampons to the conclusion that state product liability law was pre-empted when it involved an inadequate warning claim. This Court's analysis in *Silkwood* demonstrates that such aborted reasoning may result in an erroneous finding of pre-emption. It does not follow from the fact that an agency or statute regulates a field or sets standards that compensatory awards under state law are therefore precluded. This Court has recognized that the two areas of law can coexist and indeed are necessary to providing a complete legal system. Federal laws may set the standard and impose penalties for noncompliance. But even where a regulated party complies with those regulations, it will not be immune from compensatory tort claims by individuals injured by its conduct. *Silkwood v. Kerr-McGee*, 464 U.S. at 625-26.

This Court has the opportunity of correcting this erroneous interpretation of the pre-emption doctrine in an area constantly being litigated. No fewer than 18 courts have reached the incorrect conclusion that state tort laws are pre-empted by these federal regulations. [See cases cited in *Berger v. Personal Products*, 115 Wn. 2d at 272, n.9.] This in turn has resulted in a large number of plaintiffs being denied their right to compensation. No other case, however, is ripe for this Court's review. If the writ is granted, a timely and important issue can be resolved expeditiously.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

BERTHA BARANKO FITZER
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APPENDIX

APPENDIX

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

No. 56098-6

En Banc

ERNEST BERGER, as Personal Representative,
Appellant,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

[Filed Sep. 20, 1990]

Nature of Action: The personal representative of a decedent who had died of toxic shock syndrome brought a products liability action against the manufacturer of the tampons used by the decedent.

Superior Court: The Superior Court for Yakima County, No. 86-2-01249-3, Bruce P. Hanson, J., on April 10, 1989, granted a partial summary judgment dismissing the claims based on inadequate warnings and instructions.

Supreme Court: Holding that state law regarding inadequate warnings and instructions was preempted by federal law, the court *affirms* the judgment.

Rush, Hannula & Harkins, by *William J. Rush* and *Daniel R. Kyler*, for appellant.

Susan J. Robinson, *Gregory C. Sisk*, and *Karr Tuttle Campbell* (*George Gore*, *Victoria L. Vance*, and *Arter & Hadden*, of counsel), for respondents.

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

Number 56098-6

En Banc

ERNEST BERGER, Personal Representative of the Estate of SHEILA BERGER,

Appellant,

v.

PERSONAL PRODUCTS, INC., a foreign corporation, aka and/or merged with JOHNSON & JOHNSON BABY PRODUCTS, a foreign corporation; and JOHNSON & JOHNSON PRODUCTS, INC., a foreign corporation; and JOHNSON & JOHNSON, INC., a foreign corporation,

Respondents.

Filed Sep. 20, 1990

SMITH, J.—Appellant Ernest Berger, as personal representative of the estate of Sheila Berger, deceased, appeals from a partial summary judgment of the Yakima County Superior Court dismissing his product liability action against respondent Personal Products, Inc. We affirm the trial court.

The sole question we consider is whether under 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(b) federal law preempts a state tort action based on the claims of inadequate warnings and instructions about the risk of contracting toxic shock syndrome associated with tampon use when the product complies with federal labeling re-

quirements under 21 C.F.R. § 801.430. Appellant Berger does not dispute respondent's compliance with those regulations. We answer that federal law does preempt a state tort action under these circumstances.

On January 4, 1984, Ms. Sheila Berger, age 20, died of toxic shock syndrome alleged to have been contracted as a result of using respondent's product, "o.b. tampons." [1] In his claims against Respondent Personal Products, Inc., Appellant Berger alleged that Personal Products' tampon was unreasonably dangerous because of its faulty manufacture, faulty design, and inadequate warnings and instructions about the risk of contracting toxic shock syndrome.

Respondent Personal Products, Inc., moved for summary judgment on the claim of inadequate warnings and instructions, arguing that federal statutes and regulations preempt any state tort action based upon the adequacy of warnings when the product complies with federal labeling requirements under 21 C.F.R. § 801.430.

The trial court, the Honorable Bruce P. Hanson, Yakima County Superior Court, granted the motion for partial summary judgment, holding that, under 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(b) relating to preemption, federal law preempts a state tort action on this issue. The trial court denied a request by Appellant Berger to enter a final judgment on the warnings and in-

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[1] Toxic shock syndrome is a rare but serious disease which can be fatal. It is believed to be caused by a toxin-producing strain of bacteria called *Staphylococcus aureus*. It is also believed that the use of tampons enhances the growth of the bacteria. Teenaged girls and women under 30 years of age are reported to be more likely to develop tampon-associated toxic shock syndrome than menstruating women of other age groups. Toxic shock syndrome also occurs, however, in nonmenstruating women. The disease is characterized by a marked drop in blood pressure and a physical state of shock. Primary symptoms include a sudden fever (usually 102 degree fahrenheit or more), diarrhea, fainting or near fainting when standing up, dizziness, and a rash resembling a sunburn. 21 C.F.R. § 801.430.

structions issues pursuant to CR 54(b). Appellant Berger then stipulated to dismissal with prejudice of his remaining claims.

Appellant Berger claims that federal statutes and regulations do not preempt a state tort action based on the adequacy of warnings and instructions.

Respondent Personal Products, Inc., asserts that the regulations promulgated by the Food and Drug Administration governing labeling requirements of tampons found in 21 C.F.R. § 801.430 preempt state tort law on this issue under 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(b).

The doctrine of federal preemption is derived from the supremacy clause of the United States Constitution, article 6, section 2. Federal law preempts state law when Congress intends to occupy a given field, when state law directly conflicts with federal law, or when state law would hinder accomplishment of the full purposes and objectives of the federal law.[2] Preemption may be either express or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. Federal regulations have the same preemptive effect as federal statutes.[3]

In 1976 Congress enacted extensive and comprehensive amendments to the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 *et seq.*, which became known as the Medical Device Amendments of 1976, 90 Stat. 539, 21 U.S.C. § 360c-k. Under the amendments, all medical de-

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[2] *Alverado v. WPPSS*, 111 Wn.2d 424, 431, 759 P.2d 427 (1988), *cert. denied*, —— U.S. ——, 104 L. Ed. 2d 153, 109 S. Ct. 1637 (1989).

[3] *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-54, 73 L. Ed. 2d 664, 102 S. Ct. 3014, 3022 (1982).

vices intended for human use are required to be classified according to their potential risk in order to insure that each product receives the most appropriate form of regulatory control. The Food and Drug Administration classified tampons as Class II (performance standards) medical devices.[4]

Respondent Personal Products, Inc., asserts that section 360k(a) of the Medical Device Amendments expressly preempts any warnings or instructions claims based on state tort law. That section provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Regulations promulgated by the Food and Drug Administration pursuant to this statute reflect this expression of intent to preempt state law.

> [Section 360k(a)] prescribes a general rule that . . . no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act which relates to the safety or ef-

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[4] 45 Fed. Reg. 12, 715-18 (1980); *see also* 21 C.F.R. § 884.5460; 21 C.F.R. § 884.5470 (1988).

> fectiveness of the device or to any other matter included in a requirement applicable to the device under the act.[5]

(Italics ours.)

In 1982, in response to the discovered association between toxic shock syndrome and tampon use, the Food and Drug Administration adopted labeling requirements for tampons. The regulations required the following consumer information to appear "prominently and legibly, in a package insert or on the package, in terms understandable by the layperson": [6]

> 1. The warning signs of Toxic Shock Syndrome and what to do if the warning signs appear;
>
> 2. The statistical risk of Toxic Shock Syndrome to women using tampons;
>
> 3. The advisability of using tampons with the minimum absorbency needed to control menstrual flow;
>
> 4. The potential for avoiding the risk of getting tampon-associated Toxic Shock Syndrome by not using tampons and the potential for possibly reducing the risk of getting toxic shock syndrome by alternating tampon use with sanitary napkin use during menstrual periods;
>
> 5. The need to seek medical attention before again using tampons if Toxic Shock Syndrome warning signs have occurred in the past, or if women have any questions about Toxic Shock Syndrome or tampon use.[7]

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[5] (Italics ours.) 21 C.F.R. § 808.1(b).

[6] Former 21 C.F.R. § 801.430(d).

[7] *See* 21 C.F.R. § 801.430(d).

In addition to the information to be provided in a package insert, the following "alert statement" must appear "prominently and legibly on the package label":

> ATTENTION: Tampons are associated with Toxic Shock syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.[8]

United States District Court addressing this same issue in recent years have almost uniformly held that federal law preempts state tort actions under these circumstances.[9] The United States Court of Appeals for the Fifth Circuit has similarly ruled. In *Moore v. Kimberly-*

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[8] 21 C.F.R. § 801.430(c).

[9] *See Moore v. Kimberly-Clark Corp.*, 676 F. Supp. 731, 734-35 (W.D. La. 1987), *aff'd in part on relevant grounds, rev'd in part*, 867 F.2d 243 (5th Cir. 1989); Krause v. Kimberly-Clark Corp., No. L89-30066CA (W.D. Mich. Jan. 17, 1990); *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1063, (D. Minn. 1989); Chapman v. Playtex FP, Inc., No. 89-0718-LC (W.D. La. Nov. 17, 1989); Rockett v. International Playtex, Inc., No. 87-2870 (W.D. La. Oct. 4, 1989); Northrip v. International Playtex, Inc., No. 88-0559-CV-W-1 (W.D. Mo. Sept. 28, 1989); Parrott v. International Playtex, Inc., No. SA CV 88-491 JSL (RWRx) (C.D. Cal. May 15, 1989); Bejarano v. International Playtex, Inc., No. 87-4027 (D. Idaho May 10, 1989); *Cornelison v. Tambrands, Inc.*, 710 F. Supp. 706, 708-09 (D. Minn. 1989); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 477 (S.D. Ind. 1988); Stucker v. International Playtex, Inc., No. C-87-0440-L(b) (W.D. Ky. Feb. 26, 1988), *rev'd on other grounds*, 865 F.2d 261 (1989); Meyer v. International Playtex, Inc., No. 86-3430 (D.N.J. Dec. 1, 1988); Eason v. Tambrands, Inc., No. 87-11677-A (D.C. Tex. Nov. 29, 1988); *Lavetter v. International Playtex, Inc.*, 706 F. Supp. 722 (D. Ariz. 1988); Briggs v. International Playtex, Inc., No. 86C-540-E (N.D. Okla. Apr. 7, 1988); *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907, 909-10 (D.S.C. 1987); *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571, 1574-75 (N.D. Ga. 1987); Ignace v. Playtex Family Prods., Inc., No. 86-C-480C (W.D. Wis. Aug. 14, 1987). But see Muzatko v. International Playtex, Inc., No. 85C-1540 (E.D. Wis. May 14, 1987); Kerns v. International Playtex, Inc., No. C-1-86-297 (S.D. Ohio Apr. 18, 1988).

Clark Corp.,[10] that court affirmed the District Court's grant of summary judgment in favor of the defendant tampon manufacturer with respect to plaintiff's warnings and instructions claims. In doing so, the court concluded that state law claims based on inadequate labeling and warning statements are preempted [11] by 21 U.S.C. § 360k and 21 C.F.R. § 808.1(b).[12]

The court in *Moore* noted that:

> The FDA did not intend to preempt all state laws and regulations pertaining to tampons. This is made clear in [21 C.F.R. § 808.1(d) [13]] which provides that "[s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . ." The relevant requirements applicable under § 360k are set forth in 21 C.F.R. §§ 801.430, 884.5460, and 884.5470, which declare that tampons are a medical device covered by the Act and outline the liability and warning requirements with respect to TSS [toxic shock syndrome].[14]

The United States District Court for the District of South Carolina in *Stewart v. International Playtex, Inc.*,[15]

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[10] 867 F.2d 243 (5th Cir. 1989).

[11] While affirming the District Court's holding that plaintiff's state tort law warnings and instructions claims were preempted, the United States Court of Appeals for the Fifth Circuit reversed the district court's finding that plaintiff's state tort law design defect claims were preempted.

[12] This regulation was incorrectly cited in *Moore* as 21 C.F.R. § 801.1(d).

[13] This regulation was also incorrectly cited in *Moore* as 21 C.F.R. § 801.1(d).

[14] *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244-45, (5th Cir. 1989).

[15] 672 F. Supp. 907 (D.S.C. 1987).

granted partial summary judgment for a defendant tampon manufacturer on the ground that the Medical Device Amendments expressly preempted state law. The court in *Stewart* rejected the contention that state tort law should not be considered a state law "requirement" within the meaning of the Medical Device Amendments preemption provision defined in 21 C.F.R. § 808.1(b), stating at pages 909-10:

> On its face, this definition encompasses the actions of a court of law entering judgment against the defendant for compensatory and punitive damages based upon "inadequate warnings". The FDA has therefore determined that a state's common law —to the extent it attempts to regulate matters already addressed by the FDA—shall be considered a § 360k "requirement". South Carolina tort law is, therefore not exempt from § 360k.

At least one reported case does not recognize federal preemption in a product liability action based on inadequate warnings and instructions on the risk associated with tampon use. In *Muzatko v. International Playtex, Inc.*,[16] the United States District Court for the Eastern District of Wisconsin concluded that the Food and Drug Administration's toxic shock syndrome warnings regulations did not rise to the level of a requirement within the meaning of § 360k of the Medical Device Amendments.[17]

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[16] No. 85C-1540 (E.D. Wis. May 14, 1987). In an unpublished ruling, the court in Kerns v. International Playtex, Inc., No. C-1-86-297 (S.D. Ohio Apr. 18, 1988), held that the plaintiffs' inadequate warnings and instructions claims were not preempted by federal statute and regulations.

[17] In a case involving an intrauterine device, *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1151 (D. Or. 1989), the court noted that there appeared to be a doctrinal split in the federal appellate courts on whether state tort liability constitutes a requirement within the terms of the Medical Device Amendments. However, the court held

The court in that case relied upon *O'Gilvie v. International Playtex, Inc.*,[18] which indicated that the federal regulations were merely minimum standards. The issue of *O'Gilvie*, however, was the propriety of a jury instruction. The question of preemption was not raised and therefore was not an issue.

On the basis of the facts in this case and the authorities cited, we conclude that under 21 U.S.C. § 360k and 21 C.F.R. § 808.1(b), federal law clearly preempts state tort law on tampon labeling and warnings requirements for toxic shock syndrome. The trial court was correct in granting the motion for partial summary judgment in this case based on federal preemption.

/s/ Smith

We affirm the trial court.

WE CONCUR:

/s/ Callow, C.J.

/s/ Dore, A/C/J

/s/ Brachtenbach, J.

/s/ Andersen, J.

/s/ Durham, J.

/s/ Utter, J.

/s/ Dolliver, J.

/s/ Guy, J.

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that the Medical Device Amendments do not apply to the intrauterine device at issue in that case.

[18] 609 F. Supp. 817 (D. Kan. 1985), *aff'd in part, rev'd in part*, 821 F.2d 1438 (10th Cir. 1987).

THE SUPREME COURT OF WASHINGTON

No. 56098-6

Yakima County No. 86-2-01249-3

ERNEST BERGER, Personal Representative of the Estate of SHEILA BERGER,
Appellant,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

MANDATE

THE STATE OF WASHINGTON TO: The Superior Court of the State of Washington in and for Yakima County.

This is to certify that the opinion of the Supreme Court of the State of Washington filed on September 20, 1990, became the decision terminating review of this court in the above entitled cause on November 19, 1990. This cause is mandated to the superior court from which the appeal was taken for further proceedings in accordance with the attached true copy of the opinion.

Pursuant to Rule of Appellate Procedure 14.3, costs are taxed as follows: $596.00 awarded to the Respondents Johnson & Johnson, et al. and against Appellants Berger.

Order Denying Motion for Reconsideration was entered herein on November 19, 1990. Copy Attached.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seal of said [SEAL] Court at Olympia, this 21st day of November, 1990.

/s/ C. J. Merritt
C. J. MERRITT
Clerk of the
Supreme Court
State of Washington

cc: William J. Rush
Daniel R. Kyler
Susan J. Robinson
Gregory C. Sisk
Victoria Vance
Yakima Co. Clerk
West Publishing
Reporter

THE SUPREME COURT OF WASHINGTON

No. 56098-6

ERNEST BERGER, as Personal Representative,
Appellant,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

ORDER DENYING
MOTION FOR RECONSIDERATION

The Court having decided unanimously that the appellant's motion for reconsideration should be denied,

It is ordered that the motion be and it hereby is denied.

Dated this 19th day of November, 1990.

/s/ Keith M. Callow
Chief Justice

IN THE SUPERIOR COURT
OF THE STATE OF WASHINGTON
IN AND FOR YAKIMA COUNTY

No. 86-2-01249-3

ERNEST BERGER, *et al.*,
Plaintiffs,

vs.

JOHNSON & JOHNSON PRODUCTS, INC., *et al.*,
Defendants.

MEMORANDUM OPINION

This action is brought by the Personal Representative of the Estate of Sheila Berger who died from toxic shock syndrome alleged to have been contracted as a result of using defendant's o.b. tampons.

Among other claims, plaintiff alleges that defendants were negligent in failing to provide adequate warnings and instructions with this product.

Defendants have moved for partial summary judgment based upon the issue of federal pre-emption, it being claimed that the Food and Drug Administration's tampon labeling regulations pre-empts state tort laws. It is not claimed by plaintiffs that defendant's tampon labeling did not comply with such regulations, but rather that such regulations set only minimum requirements and a factual issue remains as to the adequacy of such labeling.

Each party has furnished the Court memoranda and supporting material demonstrating a thorough and even exhaustive search and preparation on this issue.

Defendants' motion is primarily based upon Title 21 U.S.C. Section 360k which provides in part:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

and Section 808.1(b) of 21 C.F.R.:

> "[Section 360k(a)] of the [Amendments] contains special provisions governing the regulation of devices by State and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act."

Other statutes and regulations are cited as supportive of their position but need not be repeated or referred to herein.

The Court has read many cases cited and finds the following contained in defendants' various memoranda as very persuasive:

> *Edmondson v. International Playtex, Inc.*, No. C85-306R (U.S.D.C. N.D. Ga.)

Ignace v. International Playtex, Inc., No. 86-C-480-C (U.S.D.C. N.D. WI)

Stewart v. International Playtex, Inc., 672 F. Supp. 907 (D.SC Oct. 8, 1987)

Moore v. Kimberly-Clark Corp., Civil Action No. 86-0560 (U.S.D.C. W.D. La., Dec. 23, 1987)

Lavetter v. International Playtex, Inc., No. 84-788-TUC-RMB (U.S.D.C. D. Az., Jan. 22, 1988)

Stucker v. International Playtex, Inc., No. C-87-0440-L(B) (U.S.D.C. W.D. Ky., Feb. 25, 1988)

To continue this opinion in depth would be only to parrot much of the reasoning in those cases cited as to the issue of federal pre-emption generally and Title 21 U.S.C. Section 301 et. seq. and applicable regulations specifically.

Therefore, defendants' motion for partial summary judgment is granted.

DATED this 14th day of March, 1989.

/s/ Bruce P. Hanson
JUDGE BRUCE P. HANSON

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.S.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You have requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of section 521 of

the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to a device only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in *National Women's Health Network, et al. v. A.H. Robins Company, Inc.*, No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injunctive remedies. This advisory opinion does not address the merits of the application of such remedies in any action filed by the network in the State of Massachusetts or any other State.

Sincerely yours,

/s/ Joseph P. Hile
JOSEPH P. HILE
Associate Commissioner
for Regulatory Affairs

cc: Jeanne Baker, Esq.
David Fine, Esq.
Silverglate, Gertner,
Baker & Fine
88 Broad Street
Boston, Massachusetts 02110

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, Washington 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,

/s/ Joseph M. Sheehan
JOSEPH M. SHEEHAN
Chief, Regulations Staff

Enclosures

January 14, 1987

Marlys Marshall, Esq.
8100 East 22nd Street, North
Building 1200
Wichita, Kansas 67226-2312

Dear Ms. Marshall:

As we discussed in our telephone conversation today, I am enclosing a copy of an advisory opinion issued by FDA, stating that state requirements respecting available legal remedies are not "requirements with respect to a device" within the meaning of 21 U.S.C. § 360(k)(a) and consequently, are not preempted by federal law.

If I may be of further assistance, please call me at (301) 443-4350.

Very truly yours,

/s/ Beverly Rothstein
BEVERLY ROTHSTEIN
Associate Chief Counsel
for Enforcement

Enclosures

STATUTES INVOLVED

21 U.S.C. § 360k. State and local requirements respecting devices.

(a) General Rule.

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360(g)(e). Remedies.

The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

ART. 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

Subpart A—General Provisions

§ 808.1 Scope

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupa-

tions that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and other, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohiibtion has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted

and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption.

As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980]

§ 808.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Compelling local conditions" includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

(c) "More stringent" refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act.

(d) "Political subdivision" or "locality" means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

(e) "State" means a State, American Samoa, the Canal Zone, the Commonwealth of Puerto Rico, the District of Columbia, Guam, Johnston Island, Kingman Reef, Midway Island, the Trust Territory of the Pacific Islands, the Virgin Islands, and Wake Island.

(f) "Substantially identical to" refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

No. 90-1305

Supreme Court, U.S.
FILED
MAR 20 1991
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ERNEST BERGER, Personal Representative
of the Estate of SHEILA BERGER,

Petitioner,

—v.—

PERSONAL PRODUCTS, INC., et al.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE WASHINGTON STATE SUPREME COURT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Respondents reformulate the question presented as follows:

> Does federal law preempt a state tort action based on the claims of inadequate warnings and instructions about the risk of contracting toxic shock syndrome associated with tampon use when the product complies with federal labelling requirements?

PARTIES

Petitioner is Ernest Berger as Personal Representative of the Estate of Sheila Berger.

Respondents are Johnson & Johnson (misnamed in Washington Supreme Court opinion as "Johnson and Johnson, Inc."), Personal Products Company (misnamed in Washington Supreme Court opinion as "Personal Products, Inc."), and Johnson & Johnson Medical, Inc., f/d/b/a Johnson & Johnson Products, Inc. Johnson & Johnson is a corporation organized and existing under the laws of New Jersey with its principal place of business in New Brunswick, New Jersey. It is a publicly held corporation. Johnson & Johnson has no parent corporation and has no subsidiaries or affiliates other than wholly-owned subsidiaries. Personal Products Company, a division of McNeil-PPC, Inc., and Johnson & Johnson Medical, Inc. are wholly-owned subsidiaries of Johnson & Johnson.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

No. 90-1305

ERNEST BERGER, Personal Representative
of the Estate of SHEILA BERGER,

Petitioner,

—v.—

PERSONAL PRODUCTS, INC., et al.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE WASHINGTON STATE SUPREME COURT

BRIEF IN OPPOSITION

TO: The Honorable Chief Justice and Associate Justices of the Supreme Court of the United States:

Respondents Johnson & Johnson, Personal Products Company, and Johnson & Johnson Medical, Inc. (collectively, "Personal Products Co.") respectfully submit that certiorari should not be granted in this case. In a unanimous *en banc* decision, the Washington State Supreme Court held that a state tort action based on the claims of inadequate warnings and instructions concerning the risk of contracting toxic shock syndrome ("TSS") associated with tampon use are preempted by federal law when the product complies with federal labelling requirements. That decision is consistent with

precedent from this Court mandating preemption of state law where Congress or a federal regulatory agency has expressed an intent to preempt. The decision is also in accord with the decisions of every other appellate court—both state and federal—that has considered this precise question.[1]

Petitioner's argument against preemption—and for this Court's review—depends upon an oversimplified and misconceived version of the law. In the Medical Devices Amendments ("MDA") of 1976 to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the regulations promulgated thereunder, 21 CFR Part 800 *et seq.*, Congress and the Food and Drug Administration ("FDA") have expressed an intent to preempt state law where a manufacturer has complied with specific regulations concerning a medical device. There is no question that the FDA's regulations concerning tampon warnings and instructions are specific requirements concerning tampons and that tampons are classified as medical devices. In addition, there is no question that respondents complied with the federal regulations governing tampon warnings and instructions. Thus the Washington Supreme Court decision is plainly correct in finding in favor of preemption.

Because the decision of the Washington Supreme Court correctly applies this Court's precedents, and because its holding is consistent with every other appellate decision addressing the issue, there is no reason for this Court to grant certiorari.

---

1 A list of the decisions that are consistent with the Washington Supreme Court's decision is contained in Appendix A.

STATEMENT OF THE CASE

The petition requests review of the Washington Supreme Court's unanimous *en banc* affirmance of the trial court's grant of partial summary judgment. *Berger v. Personal Products, Inc.*, 115 Wash. 2d 267, 797 P.2d 1148 (1990). In granting partial summary judgment, the trial court dismissed that portion of petitioner's product liability claim that was based on the alleged failure of Personal Products Co. to adequately warn its tampon users of the risk of TSS. Following a host of prior decisions directly on point, the Yakima County Superior Court ruled that federal law—21 U.S.C. § 360k(a) and the relevant regulations promulgated by the FDA—preempts state tort claims for inadequate TSS warnings and instructions where a manufacturer has complied with federal regulatory standards. *Berger v. Johnson & Johnson Products, Inc.*, No. 86-2-01249-3 (Sup. Ct. Yakima Co. Wash. March 14, 1989).

This decision was then reviewed and unanimously affirmed by the Washington Supreme Court. The Court's decision is consistent with the decisions of thirty-five other courts that have considered this precise issue.

In seeking a writ of certiorari, petitioner attempts to erect and defeat a straw man. Petitioner misreads the *Berger* decision as holding that the MDA preempts *all* state law claims. After positing this fictional "holding," petitioner then attacks it by relying on cases that do *not* involve the FDA's regulations concerning tampons or TSS and by relying on cases that do *not* involve interpretation of the MDA. These cases are not on point.

The Washington Supreme Court's decision does not broadly displace all state tort law. It does not hold that tort claims based on an alleged failure to comply with federal regulations concerning tampon warnings are preempted, and it does not suggest that tort claims based on design defect are displaced. In fact, petitioner had asserted a design defect

claim before the trial court and then voluntarily dismissed that claim.

What the *Berger* decision, and every other reasoned decision on this issue, asserts is consistent with what the FDA has determined in its regulations, *i.e.*, that state requirements are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . ." *Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 273, 797 P.2d at 1151, *quoting Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244-45 (5th Cir. 1989). Because the decisions on the preemption of state law claims concerning tampon warnings are consistent, clear, and correct, there is no reason for this Court to grant certiorari to review this case.

REASONS FOR DENYING THE WRIT

I. The *Berger* Decision Does Not Raise a Significant Issue Concerning the Supremacy Clause and a State's Right to Provide Tort Claims

A. Under the Constitution's Supremacy Clause, Federal Law May Explicitly or Implicitly Preempt State Law, Including State Tort Claims

It is a "familiar and well-established principle that the Supremacy Clause, U.S. Const., art. VI, cl. 2, invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 712 (1985), *quoting Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824). This Court has repeatedly recognized a variety of ways in which federal law may displace state law. *See generally California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 581 (1987); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984). "Preemption may be either express or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's lan-

guage or implicitly contained in its structure and purpose.' " *Fidelity Fed. Sav. and Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 152-53 (1982), *quoting Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

Although the case involves express preemption, Congress' intent to displace state law may be implied because the federal regulatory scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it or because the federal regulation touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject or because the object sought to be obtained by federal law and the character of obligations imposed by it may reveal the same purpose. *Jones v. Rath Packing Co.*, *supra*, 430 U.S. at 525; *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Moreover, state law can be preempted by federal regulations as well as by federal statutes. *See Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 369 (1986); *Hillsborough County v. Automated Medical Laboratories, Inc.*, *supra*, 471 U.S. at 713; *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984); *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, *supra*, 458 U.S. 141.

Even where federal regulations have not completely displaced state regulation in a specific area, state law is supplanted to the extent that it actually conflicts with federal law—that is, where "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). In this case, because Congress and the FDA expressed an intent to preempt state law, there is no need to consider these issues of implied preemption.

Petitioner is plainly wrong in suggesting that common law claims brought in state court can never be preempted. As this Court has stated,

> [R]egulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy. Even the States' salutary effort to redress private wrongs or grant compensation for past harm cannot be exerted to regulate activities that are potentially subject to the exclusive federal regulatory scheme.

San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959). *See International Paper Co. v. Ouellette*, 479 U.S. 481 (1987) (holding that, in the circumstances presented, a claim for damages and injunctive relief under Vermont's common law of nuisance was preempted by the Clean Water Act). *Chicago & N.W. Trans. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 326-27 (1981). *See also Silkwood v. Kerr-McGee Corp.*, *supra*, 464 U.S. at 256.

B. The Federal Regulatory Scheme at Issue Preempts Differing or Additional State Law Requirements Concerning the Adequacy of Tampon Warnings

1. Congress and the FDA Intended to Preempt State Law Where the FDA Promulgates Specific Device Requirements

In this case, the preemption analysis begins with the 1976 Medical Device Amendments to the FDCA, 21 U.S.C. § 301 *et seq.* According to the Senate Committee Report that reviewed it, the MDA's purpose was to encourage the research and development of increasingly sophisticated and critically important medical devices, as well as to ensure that "the FDA has the proper authority to regulate that process so that Americans are not put at risk from the use of unsafe and ineffective medical devices." S. Rep. No. 33, 94th Cong., 1st Sess. (1975), *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1071. Congress also sought to ensure that, once the FDA had addressed an issue of safety or efficacy, a state could not create an undue burden by imposing other requirements:

> The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.

H.R. Rep. No. 853, 94th Cong., 2d Sess., at 45 (1976). As one court stated, Congress intended "to prohibit, by the doctrine of express preemption, the proliferation of multiple, diverse, state by state requirements." *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907, 909 (D.S.C. 1987).

Under the MDA, the FDA is authorized to classify medical devices in three categories, depending upon the sufficiency of information concerning their safety and efficacy. 21 U.S.C. § 360. The MDA delegated to the FDA the power to establish "performance standards" with regard to all devices categorized in Class II. 21 U.S.C. § 360d(a)(1).

The preemptive effect of the FDA performance standards is established in § 360k(a) of the MDA:

> (a) General Rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(*See* Appendix B). A state, or a political subdivision, may avoid preemption by applying for an exemption pursuant to § 360k(b), but that provision is not at issue here because Washington State has not applied for an exemption as to state law remedies regarding tampon labelling.

Pursuant to the MDA, the FDA promulgated specific regulations addressing preemption. 21 C.F.R. Part 808. The FDA regulations provide that

> [s]tate or local requirements are preempted only when the Food and Drug Administration has established *specific counterpart regulations* or there are *other specific requirements applicable* to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. . . .

21 C.F.R. § 808.1(d) (emphasis added) (*See* Appendix C).

To the extent that the FDA's regulations preempt state law, there is no question that the preemption includes court decisions. First, as noted above, it is well established that the preemption doctrine applies to supersede common law claims brought in state court. *San Diego Bldg. Trades Council v. Garmon*, *supra*, 359 U.S. at 247; *International Paper Co. v. Ouellette*, *supra*, 479 U.S. 481; *Chicago & N.W. Trans. Co. v. Kalo Brick & Tile Co.*, *supra*, 450 U.S. at 326-27; *Silkwood v. Kerr-McGee Corp.*, *supra*, 464 U.S. at 256. Second, the FDA explicitly included court decisions in the ambit of state requirements that would be preempted by its regulations. 21 C.F.R. § 808.1(b) (Appendix C). In relevant part, that regulation provides that after the effective date of the MDA,

> no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(Emphasis added.)

There can be no clearer statement by Congress or the FDA of an intent to preempt state law—including state tort claims—with regard to any medical device for which the FDA establishes specific requirements.

2. The FDA Promulgated Regulations Containing Specific Requirements Concerning Tampon Warnings, Thereby Preempting State Law

In February 1980, the FDA classified tampons as Class II medical devices. 21 C.F.R. §§ 884.5460 and 884.5470 (*See* Appendix D). Subsequently, on June 22, 1982, the FDA promulgated a regulation setting forth specific and mandatory labelling requirements regarding the risk of TSS associated with tampon use. 21 C.F.R. § 801.430 (*See* Appendix E). That regulation *requires* that specific language be included both in and on every package of tampons, and it mandates that such warning *shall appear* prominently and legibly on the package label.[2]

---

2 At the time relevant to this action, that regulation stated in pertinent part as follows:

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement *shall* appear prominently and legibly on the package label:

Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

(d) The consumer information required by this section *shall* appear prominently and legibly, in a package insert on the package, in terms understandable by the layperson and *shall* include statements concerning:

(1)(i) Warning signs to TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to

There is no question that the FDA's regulation of tampon warnings is a "requirement" within the meaning of 21 C.F.R. § 808.1(b) and (d), quoted *supra*, which provide for preemption of state or local requirements relating to tampon labelling. Accordingly, all state law requirements regarding the adequacy of tampon labelling with respect to TSS warnings, including court decisions, are preempted where the manufacturer has complied with the FDA's regulations. 21 U.S.C. § 360k(a); 21 C.F.R. § 808.1(b).

C. The Federal Regulatory Scheme Expressly Preempts Competing Requirements Established by State Product Liability Law Concerning Tampon Warnings

Petitioner argues that the MDA does not expressly preempt all state product liability law and hence state tort actions based on inadequate tampon warnings claims are not preempted. Respondents agree that the MDA does not automatically displace all state tort law. What the MDA does is

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women under 30 years of age and teenage girls, the estimated incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

. . .

(f) Any menstrual tampon that is not labeled as *required* by this section and that is initially introduced or initially delivered for introduction into commerce after December 20, 1982, is misbranded pursuant to sections 502(a) and 201(n) of the act.

(Emphasis added.) The FDA has subsequently amended this regulation. A copy of the 1990 amended regulation is produced at Appendix F.

provide the framework requiring preemption when the FDA promulgates specific requirements for medical devices. Petitioner's argument simply ignores the FDA's specific regulations that *do* expressly preempt state law claims for tampon warnings that comply with FDA regulations. It is those regulations, promulgated with proper authority, that mandate preemption in this case.

Petitioner also ignores the substantial body of law that uniformly interprets those precise regulations as preempting state product liability claims based on the adequacy of tampon warnings. As the Washington Supreme Court and many other courts have determined, those regulations reflect the "expression of intent to preempt state law." *Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 271, 797 P.2d at 1150. (*See also* decisions listed in Appendix A.)

Petitioner cannot find support for its position in the language or history of either the MDA or the regulations promulgated thereunder. Unable to find support in the one statute that governs this case, petitioner turns to other statutes that are not controlling here. Thus petitioner argues that the legislative history of the 1938 FDCA does not show an intent to preempt state law. That argument is misplaced. The relevant statute is the MDA, not the FDCA of 1938. The FDCA history was superseded in 1976 when Congress enacted the MDA, which explicitly preempts state law where such law is inconsistent with FDA regulations. 21 U.S.C. § 360k(a) (Appendix B). Pursuant to authority conferred by the MDA, the FDA determined to preempt all competing state regulation, including court decision, by promulgating specific requirements for medical devices. 21 C.F.R. § 808.1(b) (Appendix C). The FDA has, in fact, promulgated a detailed requirement on tampon warnings and instructions. 21 C.F.R. § 801.430 (Appendix E). The history of the 1938 FDCA that petitioner cites has no bearing on the preemptive effect of regulations promulgated under authority granted by a later Congress, and this Court should not grant review based on irrelevant legislative history. *See Hillsborough County v. Automated Medical Laboratories, Inc.*, *supra*, 471 U.S. at

714 (suggesting that subsequent history revealing a change in Congress' or the FDA's position supersedes previous history).

Turning even further afield, petitioner also attempts to rely on the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and a case decided under FIFRA. *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). That reliance is equally misplaced. FIFRA established minimum requirements for labeling claims and it did not preempt a state's right to set higher standards. Moreover, FIFRA has its own regulatory and legislative history, and it is absurd to suggest that the FDA—and this Court—should be bound by the interpretations of this entirely different statute. Lastly, a recent Eleventh Circuit decision expressly rejected *Ferebee* and held that FIFRA had implicitly preempted state tort claims based on labelling. *Papas v. The Upjohn Company*, No. 89-3752, 1991 U.S. App. LEXIS 3277 (11th Cir. Feb. 28, 1991). Thus, *Ferebee* is not only not on point, but it is also of questionable precedential value.

In contrast to regulations promulgated under FIFRA, which set only minimum requirements, the FDA's regulations concerning warning requirements on tampon packaging for TSS are detailed, exacting and exclusive. *See, e.g., Stewart v. International Playtex, Inc., supra*, 672 F. Supp. at 910 (distinguishing *Ferebee* because of the differences between the regulatory scheme promulgated under the MDA and regulations dealing with pesticide labelling). Those requirements dictate the exact language and content of the TSS warnings which must appear on and in all boxes of tampons. The *Berger* decision was correct in finding that competing state standards cannot stand without imposing an undue burden on commerce. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess., at 45 (1976) (Congress sought to prevent "a substantial number of differing requirements applicable to a medical device . . . imposed by jurisdictions other than the Federal government").

II. There is No Conflict Between *Berger* and any Other Decision Warranting this Court's Review

A. There is No Conflict Among the Appellate Courts that Have Considered the Preemptive Effect of the FDA's Tampon Regulations

The Washington Supreme Court's decision in *Berger* is consistent with the only federal Court of Appeals that has examined this precise issue. *Moore v. Kimberly-Clark Corp.*, *supra*, 867 F.2d 243. The *Berger* decision is also consistent with the only state court of last resort that has considered this issue. *Poloney v. Tambrands, Inc.*, 399 S.E.2d 208 (Ga. 1991). Both *Moore* and *Poloney* hold that where a manufacturer complies with federal regulations concerning warnings for TSS on tampon packaging, state law for inadequate warnings is preempted by federal law. Thus, there is no conflict between the *Berger* decision and any decision from a federal Court of Appeals or a state court of last resort warranting this Court's review.

In addition, thirty-five other federal district courts and lower state courts have also considered this issue; thirty-three have found that the federal regulations preempt state law concerning the adequacy of the TSS warnings on tampon packages. (*See* decisions listed in Appendix A.)

Of the thirty-eight decisions that have addressed the issue, only two lower court decisions, both unpublished, have held that the federal scheme does not preempt state law regarding tampon warnings. Neither decision is well-reasoned.[3] More-

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3 One of those cases, *Muzatko v. International Playtex, Inc.*, No. 85-C 1540 (E.D. Wis. May 14, 1987), relied on *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1428 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988), which did not even address this issue. *See infra* p. 15. Thus, it is utterly unpersuasive. *See Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 274-75, 797 P.2d at 1151-52; *Ignace v. International Playtex, Inc.*, No. 86-C-480C, *slip op.* at 13, n.5 (W.D. Wis. Aug. 14, 1987); *Lavetter v. International Playtex*, 706 F. Supp. 722,

over, these two aberrational decisions cannot be considered a conflict in the face of thirty-six consistent decisions.[4] It is thus easy to understand why petitioner did not address either decision.

B. Other Cites that Petitioner Relies Upon Fail to Create a Conflict with the *Berger* Decision

Petitioner ignores the consistent body of cases that have considered FDA regulations covering tampons and TSS, and instead attempts to invoke this Court's discretionary review

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723 (D. Ariz. 1988); *Stucker v. International Playtex, Inc.*, No. C87-0440-L(B), *slip op.* at 5-6 (W.D. Ky. Feb. 26, 1988). In addition, *Muzatko* has not been followed by any subsequent court, including two sitting in the same state. *See Ignace v. International Playtex, Inc.*, *supra*, No. 86-C-480C; *Mishlove v. Herman, M.D.*, No. 009-450 (Cir. Ct. Milwaukee Co. Wis. Nov. 29, 1989). *See also Bowden v. Tambrands, Inc.*, No. 85L 21095 (Cir. Ct. Cook Co. Ill. July 9, 1990) (declining to follow *Muzatko*).

The court in the other decision, *Kerns v. International Playtex, Inc.*, No. C-1-86-297, slip op. at 2 (S.D. Ohio Apr. 15, 1988), denied partial summary judgment on the issue of TSS warning stating that, because other issues remained open in the case, "[t]he granting of a partial summary judgment, in view of the differing judicial decisions, would lend little to a just final determination of this dispute among the parties and, as a practical matter, would not shorten the trial or lessen the parties' obligation to present evidence." This is not a reasoned opinion, and no court has followed it.

4 Even if the two district court decisions were inconsistent with the *Berger* decision, they would not create a conflict so as to warrant this Court's discretionary jurisdiction. *See* Sup. Ct. R. 10.1(b) (indicating that this Court will not generally grant jurisdiction unless a decision from a state court of last resort on a federal question "conflicts with the decision of another state court of last resort or of a United States court of appeals"). *See also Forsyth v. Hammond*, 166 U.S. 506, 513-15 (1897) (per Brewer, J.) (stating that this Court's certiorari jurisdiction "is a power which will be sparingly exercised, and only when the circumstances of the case satisfy us that the importance of the question involved, the necessity of avoiding conflict between two or more Courts of Appeal, or between Courts of Appeal and the courts of a State, or some matter affecting the interests of this nation in its internal or external relations, demands such exercise").

relying on two inapposite decisions involving hearing aid regulations. In *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981), and *New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 384 A.2d 795 (1978), the courts held that state laws governing the dispensing and fitting of hearing aids were not preempted by FDA regulations. Neither of those decisions are applicable here because the FDA had not promulgated specific requirements in those areas. *Smith v. Pingree*, *supra*, 651 F.2d at 1021, 1025; *New Jersey Guild of Hearing Aid Dispensers v. Long*, *supra*, 384 A.2d at 811-12.

The Fifth Circuit in *Moore v. Kimberly-Clark Corp.*, *supra*, 867 F.2d at 246-47, found this distinction to be critical in a case involving the preemptive effect of the FDA's regulation concerning tampon warnings. It held that, unlike the hearing aid regulations at issue in *Smith*, state law claims based on inadequate tampon labelling and warnings concerning TSS were preempted because the FDA had promulgated specific requirements controlling tampon warnings.

Petitioner next attempts to create a conflict between *Berger* and a Tenth Circuit decision that affirmed a jury verdict in a TSS case. *O'Gilvie v. International Playtex, Inc.*, *supra*, 821 F.2d 1428. However, as the Washington Supreme Court and other courts have recognized, the issue of preemption was not raised in that case. *Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 275, 797 P.2d at 1152; *Stewart v. International Playtex, Inc.*, *supra*, 672 F. Supp. at 910; *Lavetter v. International Playtex*, *supra*, 706 F. Supp. 722. The *O'Gilvie* decision is not on point and does not conflict with the holding in *Berger*.

Petitioner also asserts that there is a conflict between *Berger* and letters written by FDA staff members. Resort to such communications highlights the inherent lack of merit in the petition. According to FDA regulations, any opinion rendered by a staff member of the FDA "does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed." 21 C.F.R. § 10.85(k). Moreover, these letters

merely state that general tort remedies are not preempted by the MDA. Regardless of petitioner's attempts to stretch these letters, they *do not* conflict with the Washington Supreme Court's decision—indeed, these letters do not even address the preemptive effect of the specific requirements regulating tampon warnings.

Similarly, an FDA advisory opinion offered by petitioner, *see* Petitioner's Appendix at 17a-18a, fails to create a conflict. That opinion merely states that state law remedies available to those injured by Dalkon shield IUDs marketed *before* the MDA was passed are not preempted by the subsequent passage of the MDA. Rather than supporting the petitioner, this advisory opinion aids the respondents by emphasizing that state law requirements are preempted "when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act. . . ." Pet. Appendix at 18a.[5]

Finally, contrary to petitioner's claims, the *Berger* decision is consistent with this Court's opinion in *Silkwood v. Kerr-McGee Corp.*, *supra*, 464 U.S. 238. In that decision, this Court found that Congress had not intended to preempt state law remedies that were available to those injured by nuclear incidents. In reaching this conclusion, this Court relied on the legislative history of the Price-Anderson Act, in which Congress specifically considered the survival of state law remedies for those who are injured by nuclear accidents. *Id.* at 252. The Court held that the state law remedies were not preempted because the possibility of conflict created by a state decision "was something that Congress was quite willing to accept." *Id.* at 256.

Unlike the legislative intent at issue in *Silkwood*, both Congress and the FDA have expressed a clear intent in the MDA and in the regulations promulgated thereunder to preempt

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5 In support of this clearly correct interpretation, respondents have attached to this brief as Appendix G a letter written by the FDA's Chief Counsel attesting that the question of preemption depends upon the circumstances of each particular case.

state law claims with regard to requirements established for medical devices. Thus, there is no conflict between *Silkwood* and *Berger*.

* * *

The Washington State Supreme Court and thirty-five other courts have agreed that where a manufacturer complies with detailed federal regulations, state tort claims based on the adequacy of tampon warnings are expressly preempted by federal law. This uniform view is consistent with this Court's preemption decisions. None of the appellate courts that have analyzed the issue have reached a contrary conclusion, nor could a contrary conclusion be reached upon consideration of the statutory and regulatory schemes. Accordingly, there is no reason for this Court to grant the petition.

CONCLUSION

For all reasons set forth above, the petition for Writ of Certiorari should be denied.

Respectfully submitted,

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APPENDICES

Courts Finding Preemption of State Law Claims Regarding Tampon Warnings

Federal Court of Appeals

1. *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989)

District Courts

2. *Ignace v. International Playtex, Inc.*, No. 86-C-480C (W.D. Wis. Aug. 14, 1987)
3. *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987)
4. *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907 (D.S.C. 1987)
5. *Perrotta v. International Playtex, Inc.*, No. 86-8099-CIV-KEHOE (S.D. Fla. Nov. 9, 1987)
6. *Moore v. Kimberly-Clark Corp.*, 676 F. Supp. 731 (W.D. La. 1987), *aff'd in part and rev'd in part*, 867 F.2d 243 (5th Cir. 1989)
7. *Lavetter v. International Playtex, Inc.*, 706 F. Supp. 722 (D. Ariz. 1988)
8. *Stucker v. International Playtex, Inc.*, No. C-87-0440-L(B) (W.D. Ky. Feb. 26, 1988), *rev'd on other grounds*, 865 F.2d 261 (6th Cir. 1988)
9. *Briggs v. International Playtex, Inc.*, No. 86C-540-E (N.D. Okla. Apr. 7, 1988)
10. *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988)
11. *Needham v. International Playtex, Inc.*, No. 87-152 (E.D. Ky. Oct. 25, 1988), *aff'd on reconsideration*, 1989 U.S. Dist. LEXIS 800 (Jan. 26, 1989)
12. *Gilbert v. Kimberly-Clark Corp.*, No. 87-C-470-E (N.D. Okla. Nov. 4, 1988)

13. *Meyer v. International Playtex, Inc.*, 724 F. Supp. 288 (D.N.J. 1988)

14. *Jones v. Tambrands, Inc.*, No. C87-0102 (N.D. Iowa Dec. 2, 1988)

15. *Cornelison v. Tambrands, Inc.*, 710 F. Supp. 706 (D. Minn. 1989)

16. *Bejarano v. International Playtex, Inc.*, 750 F. Supp. 443 (D. Idaho 1989)

17. *Parrott v. International Playtex, Inc.*, No. SA CV 88-491 JSL (RWRx) (C.D. Cal. May 15, 1989)

18. *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058 (D. Minn. 1989)

19. *Rockett v. International Playtex, Inc.*, No. 87-2870 (W.D. La. Oct. 2, 1989)

20. *Chapman v. Playtex FP, Inc.*, No. 89-0718-LC (W.D. La. Nov. 17, 1989)

21. *Krause v. Kimberly-Clark Corp.*, 749 F. Supp. 164 (W.D. Mich. 1990)

22. *Northrip v. International Playtex, Inc.*, 750 F. Supp. 402 (W.D. Mo. 1990)

STATE COURTS

23. *Berger v. Personal Products, Inc.*, 115 Wash. 2d 267, 797 P.2d 1148 (Wash. 1990)

24. *Poloney v. Tambrands, Inc.*, 399 S.E.2d 208 (Ga. 1991)

25. *Craig v. Kimberly-Clark Corp.*, No. 86-2-14780-2 (Sup. Ct. King Co. Wash. Sept. 15, 1988)

26. *Eason v. Tambrands, Inc.*, No. 87-11677-A (Dist. Ct. Dallas Co. Tex. Nov. 29, 1988)

27. *Laughlin v. Kimberly-Clark Corp.*, No. 17715 T.D.-1 (Cir. Ct. Memphis, Tenn. Dec. 7, 1988)

28. *Case v. International Playtex, Inc.*, No. C 607960 (Sup. Ct. Maricopa Co. Ariz. Jan. 23, 1989)

29. *Berry v. Tambrands, Inc.*, Nos. 193692, 193724 (Sup. Ct. Kern Co. Cal. Feb. 27, 1989)

30. *Berger v. Personal Products, Inc.*, No. 86-2-01249-3 (Sup. Ct. Yakima Co. Wash. Mar. 14, 1989) (Memorandum Opinion), *aff'd*, 115 Wash. 2d 267, 797 P.2d 1148 (1990)

31. *Remer v. Tampax, Inc.*, No. 578755 (Sup. Ct. San Diego Co. Cal. May 10, 1989)

32. *Aase v. Tambrands, Inc.*, No. 68108 (Dist. Ct. Kootenai Co. Idaho Aug. 24, 1989)

33. *Mishlove v. Herman, M.D.*, No. 009-450 (Cir. Ct. Milwaukee Co. Wis. Nov. 29, 1989)

34. *Poloney v. Tambrands, Inc.*, No. 88-1-1084-10 (Sup. Ct. Cobb Co. Ga. Apr. 16, 1990), *aff'd*, 399 S.E.2d 208 (Ga. 1991)

35. *Bowden v. Tambrands, Inc.*, No. 85 L 21095 (Cir. Ct. Cook Co. Ill. July 9, 1990)

36. *Byrne v. International Playtex, Inc.*, No. 86309 (Nineteenth Jud. Cir. Va. July 24, 1990) (Letter Ruling)

37. *Joliff-Smith v. Tambrands, Inc.*, No. 165928 (Sup. Ct. Sonoma Co. Cal. Nov. 7, 1990)

38. *Platts v. Tambrands, Inc.*, No. 901712 (Sup. Ct. San Francisco Co. Cal. Jan. 16, 1991)

FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C.

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, c. 675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574.)

FOOD AND DRUGS, 21 CFR Ch. 1

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

* * *

Subpart A—General Provisions

§ 808.1 Scope

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an

exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or

related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b *et seq.*)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980]

* * *

§ 884.5460 Scented menstrual tampon.

(a) *Identification.* A scented menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes. This generic type of device does not include menstrual tampons treated with added antimicrobial agents or other drugs.

(b) *Classification.* Class II (performance standards).

§ 884.5470 Unscented menstrual tampon.

(a) *Identification.* An unscented menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. This generic type of device does not include menstrual tampons treated with scent (i.e., fragrance materials) or those with added antimicrobal agents or other drugs.

(b) *Classification.* Class II (performance standards).

§ 801.430 User labeling for menstrual tampons.

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Available data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c) and (d) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

> *Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.*

(d) The consumer information required by this section shall appear prominently and legibly, in a package insert or on the package, in terms understandable by the layperson and shall include statements concerning:

(1)(i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated

incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

(e) Any menstrual tampon dispensed by a vending machine is exempt from the requirements of this section.

(f) Any menstrual tampon that is not labeled as required by this section and that is initially introduced or initially delivered for introduction into commerce after December 20, 1982, is misbranded pursuant to sections 502(a) and 201(n) of the act.

§ 801.430 User labeling for menstrual tampons.

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

> *ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.*

(d) The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:

(1)(i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to

women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

(e) The statements required by paragraph (e) of this section shall be prominently and legibly placed on the package label of menstrual tampons in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (unless the menstrual tampons are exempt under paragraph (g) of this section).

(1) Menstrual tampon package labels shall bear one of the following absorbency terms representing the absorbency of the production run, lot, or batch as measured by the test described in paragraph (f)(2) of this section;

Ranges of absorbency in grams[1]	Corresponding term of absorbency
6 and under	Junior absorbency.
6 to 9	Regular absorbency.
9 to 12	Super absorbency.
12 to 15	Super plus absorbency.
15 to 18	None.
above 18	None.

[1]These ranges are defined, respectively, as follows: less than or equal to 6 grams; greater than 6 grams up to and including 9 grams; greater than 9 grams up to and including 12 grams; greater than 12 grams up to and including 15 grams; greater than 15 grams up to and including 18 grams; and greater than 18 grams.

(2) The package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

(f) A manufacturer shall measure the absorbency of individual tampons using the test method specified in paragraph (f)(2) of this section and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest 0.1 gram.

(1) A manufacturer shall design and implement a sampling plan that includes collection of probability samples of adequate size to yield consistent tolerance intervals such that the probability is 90 percent that at least 90 percent of the absorbencies of individual tampons within a brand and type are within the range of absorbency stated on the package label.

(2) In the absorbency test, an unlubricated condom, with tensile strength between 17 Mega Pascals (MPa) and 30 MPa, as measured according to the procedure in the American Society for Testing and Materials (ASTM), D 3492-83, "Standard Specification for Rubber Contraceptives (Condoms)"[1] for determining tensile strength, which is incorporated by reference in accordance with 5 U.S.C. 552(a), is attached to the large end of a glass chamber with a rubber band (see Figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched over the end of the tube and secured with a rubber band. A preweighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion

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1 Copies of the standard are available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St., N.W., Washington, DC.

needle (14 guage) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at 27 ± 1 °C. The water returns to the waterbath as shown in Figure 2. Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fuchsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first.

(3) The Food and Drug Administration may permit the use of an absorbency test method different from the test method specified in this section if each of the following conditons is met:

(i) The manufacturer presents evidence, in the form of a citizen petition submitted in accordance with the requirements of § 10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and

(ii) FDA approves the method and has published notice of its approval of the alternative test method in the FEDERAL REGISTER.

(g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.

(h) Any menstrual tampon that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into

commerce after March 1, 1990, is misbranded under sections 201(n), 502 (a) and (f) of the act.

(Information collection requirements contained in paragraphs (e) and (f) were approved by the Office of Management and Budget under control number 0910-0257)

[47 FR 26989, June 22, 1982, as amended at 54 FR 43771, Oct. 26, 1989)

[GRAPHS OMITTED]

[LETTERHEAD OF
DEPARTMENT OF HEALTH & HUMAN SERVICES]

February 20, 1987

Stephen M. McNamara, Esq.
Hyman, Phelps & McNamara, P.C.
1120 G Street, N.W.
Washington, D.C. 20009

Dear Mr. McNamara:

In a meeting today, you brought to my attention an affidavit from Marlys A. Marshall recounting a communication between her and Ms. Beverly Rothstein of my office. The affidavit has been submitted in connection with a lawsuit entitled *Edmondson* v. *International Playtex, Inc.* You have requested that I comment on the affidavit. After discussing the affidavit with Ms. Rothstein, I have the following comment.

Ms. Rothstein's statements pertained to the general issue of whether common law liability for damages for injury would be considered to be a requirement with respect to a medical device within the meaning of 21 U.S.C. § 360k(a) based on prior rulings of the Food and Drug Administration in related situations and did not state what the Food and Drug Administration would officially conclude were it to consider the question in the context of a petition for an advisory opinion. Ms. Rothstein supplied the March 8, 1984, letter from Mr. Paul Hile of FDA to Mr. Robert E. Manchester of the National Women's Health Network to Ms. Marshall as a statement of the agency's position on the specific issue addressed in that letter and conveyed the view that if asked to respond officially on the same type of issue in the future, the agency's position would be consistent. Obviously, what would be consistent would depend on the specific circumstances described. Moreover, although it is generally the case that the agency's interpretations remain uniform over time, it is obviously not possible for a member of the Office of the Chief Counsel to guarantee a specific outcome in a particular case, and certainly no firm prediction would ever be made by

a member of the Office of the Chief Counsel during a casual telephone conversation. It was specifically for that reason that Ms. Rothstein suggested to Ms. Marshall that Ms. Marshall submit a petition for an advisory opinion on the specific issue Ms. Marshall raised.

I should also note that a sentence that includes a reference to the "Chief Counsel" on page 17 of a memorandum (of which you gave me pages 16-17) is erroneous in two respects. Ms. Rothstein was not providing an "informal opinion" (other than in the sense that any statement that is not about facts is an opinion) but was providing assistance to someone wanting information, and Ms. Rothstein was not speaking as the Chief Counsel, but as an Associate Chief Counsel.

According to Ms. Rothstein, Ms. Marshall did not state that Ms. Rothstein's views would be incorporated in an affidavit and submitted in litigation in substitution for an official FDA opinion: Ms. Marshall stated that she was doing research and needed assistance.

I understand that you may use this letter in connection with the litigation and you have my permission to do so.

Sincerely yours,

/s/ THOMAS SCARLETT

Thomas Scarlett
Chief Counsel
Food and Drug Administration